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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/551,146

10/31/2006

Ulrich Kaiser

20831/0204871-US0

4136

95402

7590

05/10/2010

LEYDIG, VOIT AND MAYER  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 NORTH STETSON AVENUE  
CHICAGO, IL 60601

EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

05/10/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/551,146 | <b>Applicant(s)</b><br>KAISER, ULRICH |  |
|                              | <b>Examiner</b><br>LYLE A. ALEXANDER | <b>Art Unit</b><br>1797               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-16 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 11-15, 20 and 22-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 97/12637.
2. See the appropriate paragraph of 12/1/09 Office action for the teachings of WO 97/12637.
3. WO 97/12637 teach a sterilant challenge device to test the efficiency of air removal during a sterilization cycle. Tube(2) connect receives the sterilant and is used to determine the amount of air and non-condensable with the bore. Figure 3 show the gas collection bore(3) is conical and decreasing in cross sectional area and volume in the direction of the sensor(7). Each cross sectional area in the conical bore(3) of figure 3 is decreasing in volume with each neighboring sectional area in the direction towards the sensor(7). Additionally, page 14 lines 12-15 describe figure 3 as teaching the cross section of the bore(3) is decreasing towards the sensor(7) and has been read on the claimed "cross sectional area and a volume of each stage that is decreasing between neighboring stages." Figure 3 has been interpreted as depicting the decrease in volume between the open and end of the bore volume(5) as decreasing by 50 and 75%. Detection of sterilant by sensor(7) indicated that a sterilization cycle has been effective. Page 9 lines 25+ teach the tube(2) has a bore length of less than 30cm, preferably less

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than 20cm and most preferably less than 10cm and 7.5 cm which has been read on the claimed "channel length of less than 10cm". Page 10 lines 14-22 teaches the outer diameter of tube(2) is less than 5cm and the inner diameter of the bore(3) is less than 0.9cm and preferably 0.6cm. Page 15 lines 25+ teach that either a chemical or biological indicator can be used as the sensor(7). Page 17 lines 5+ teaches in figure 6 the compartments could be arranged "one inside another" and each compartment is individually "thermally-insulated".

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/12637.

7. See WO 97/12637 *supra*.

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8. WO 97/12637 is silent to the claimed channel length of 30-100cm and the detector volume of 100-500 microliters.

9. MPEP 21044.04(IV)(a) that changes in dimension of a device that do not cause the device to perform differently than the prior art device, is not a patentable distinction over the cited prior art. Additionally, the court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known expected results. The dimensions and volume selected for a device is a result effective variable and has the well known and expected results of accommodating the desired sample size/volume.

10. It would have been within the skill of the art to modify WO 97/12637 to have a channel length of 30-100cm and a volume of 100-500 microliter as optimization of a results effective variable.

***Allowable Subject Matter***

11. Claims 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: The cited prior art also fails to teach or suggest the claimed first stage disposed with a second stage or the first state built around an outside casing to for the second stage. Finally, the cited prior art fails to teach or suggest a packing material in a conical tapering gas collection chamber connected to an indicator.

***Response to Arguments***

13. Applicant's arguments filed 3/11/10 have been fully considered but they are not persuasive.

14. The 3/11/10 amendments have obviated the 35 USC 112 second paragraph rejections.

15. Applicant traverses the 35 USC 102 rejection over WO 97/12637 on the grounds the reference fails to teach the claimed "gas collection volume includes multiple states such that a cross sectional area and a volume of each state decreases between neighboring stages towards ... the detector volume." Figure 3 show the gas collection bore(3) is conical and decreasing in cross sectional area and volume in the direction of the sensor(7). Each cross sectional area in the conical bore(3) of figure 3 is decreasing in volume with each neighboring sectional area in the direction towards the sensor(7). Additionally, page 14 lines 12-15 describe figure 3 as teaching the cross section of the bore(3) is decreasing towards the sensor(7) and has been properly read on the claimed "cross sectional area and a volume of each stage that is decreasing between neighboring stages."

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/LYLE A ALEXANDER/  
Primary Examiner, Art Unit 1797